FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Peripheral and Central Nervous System Drugs Advisory Committee Meeting

April 14, 2023

AGENDA

The committees will discuss supplemental new drug application (sNDA) 205422 s009, efficacy supplement for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., and Lundbeck, Inc., for the proposed treatment of agitation associated with Alzheimer's dementia.

9:00 a.m.	Call to Order	**Rajesh Narendran, MD** Chairperson, PDAC
9:05 a.m.	Introduction of Committee/Conflict of Interest Statement	**Joyce Frimpong, PharmD** Designated Federal Officer, PDAC
9:15 a.m.	FDA Opening Remarks	**Tiffany R. Farchione, MD** Director Division of Psychiatry (DP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:25 a.m.	**APPLICANT PRESENTATIONS**	**Otsuka Pharmaceutical Company, Ltd.**
	Introduction	**Mary Hobart, PhD** Vice President Global Regulatory Affairs Otsuka Pharmaceutical Company, Ltd**.**
	Unmet Need in Agitation Associated with Alzheimer's Dementia	**Zahinoor Ismail, MD, FRCPC** Professor Hotchkiss Brain Institute & O'Brien Institute for Public Health University of Calgary
	Efficacy	**Robert McQuade, PhD** Executive Vice President and Chief Strategy Officer Otsuka Pharmaceutical Company, Ltd.
	Safety	**John Kraus, MD, PhD** Executive Vice President and Chief Medical Officer Otsuka Pharmaceutical Company, Ltd.

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**Alireza Atri, MD, PhD** Director Banner Sun Health Research Institute
	Benefit/Risk Summary	**Mary Hobart, PhD**
10:25 a.m.	Clarifying Questions to Applicant	
10:55 a.m.	**BREAK**	
11:05 a.m.	**FDA PRESENTATIONS**	**Shamir N. Kalaria, PharmD, PhD** Clinical Reviewer DP, ON, OND, CDER, FDA
	Efficacy	
	Safety	
12:05 p.m.	Clarifying Questions to FDA	
12:35 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	**ADJOURNMENT**	